

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

MORRIS & DICKSON CO., LLC

CIVIL ACTION NO. _____

v.

JUDGE _____

JEFFERSON B. SESSIONS, III, ET AL

MAGISTRATE JUDGE _____

**MEMORANDUM IN SUPPORT OF MOTION FOR TEMPORARY
RESTRAINING ORDER**

Movers, Morris & Dickson Co., LLC and Morris & Dickson Co., LLC d/b/a Spark Drug, Inc. (“Morris & Dickson”), submits this Memorandum in Support of its Motion for Temporary Restraining Order and represents:

Introduction

Morris & Dickson is entitled to a TRO enjoining the Drug Enforcement Agency’s May 2, 2018 License Suspension Order pending further proceedings in this case. The purpose of a TRO is to protect against irreparable injury and to preserve the status quo until the Court can render a meaningful decision on the merits. Under the traditional test for issuing a TRO or a preliminary injunction, the court must consider whether “(1) the plaintiff has a substantial likelihood of success on the merits; (2) the plaintiff would suffer irreparable injury were an injunction not granted; (3) an injunction would substantially injure other interested parties; and (4) the grant of an injunction would further the public interest.” *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 419 (5th Cir.2001).

As explained below, all four factors compel the issuance of a TRO in this case. Most critically, DEA cannot establish an imminent danger to the public health or safety from continued registration of the Morris & Dickson. This alone is a sufficient basis for issuing the TRO. *See Norman Bridge Drug Company v. Banner*, 529 F.2d 822, 828 (5th Cir. 1976) (“[i]n the absence

of that indispensable element, imminent danger to the public health and safety, all else was beside the point”).

Facts

1. Morris & Dickson was founded in, and has operated continually since, 1841, or for 177 years. It is a family owned and operated business, and is the largest independently owned and privately held drug wholesale distributor in the nation. It operates out of a single distribution center in Shreveport, LA.
2. Morris & Dickson holds two DEA licenses, one for the Shreveport distribution center, and one for a small regional transportation hub in Jefferson Parish, La. The DEA’s suspension involves both licenses, and thus, enforcement of the License Suspension Order would completely and entirely prevent Morris & Dickson’s from servicing its sector of the healthcare service industry.
3. One hundred percent of Morris & Dickson’s drug volume is shipped out of its Shreveport warehouse. Morris & Dickson’s Shreveport distribution center serves pharmacies, hospitals, and alternate care clinics such as nursing homes in 17 states. A suspension of Morris & Dickson’s Shreveport DEA registration will function to completely stop the flow of necessary drugs for surgeries, pain treatment, nursing homes, hospice, and all other legitimate, medical uses for DEA licensed narcotic drugs for Morris & Dickson’s entire market share in seventeen U.S. states.
4. On May 3, 2018, without any warning whatsoever, the DEA served Morris & Dickson with Order to Show Cause and Immediate Suspension of Registration” (hereinafter the “License Suspension Order”), a copy of which is attached hereto as **Exhibit A**. The License Suspension Order immediately suspends Morris and Dickson’s Certificates of Registration Nos. RM0314790 and RM0335732. This, in turn, requires Morris & Dickson to *immediately* halt shipment of *all*

controlled substances-including important medications used to treat seizures, cancer patients, surgical patients, to hundreds, if not thousands of customer accounts, including pharmacies and hospitals serving over 100,000 patients.

Argument

5. Morris & Dickson respectfully requests a temporary restraining order (“TRO”) to enjoin enforcement of the “License Suspension Order that the Drug Enforcement Administration (“DEA”) issued yesterday and served today on Morris & Dickson. *See In the Matter of Morris & Dickson*, Order to Show Cause & Immediate Suspension of Registration (May 2, 2018) (**Exhibit A**).

6. DEA does not allege that Morris & Dickson has provided controlled substances to anyone not licensed by DEA to receive them. Rather, DEA has taken the extraordinary step of issuing the License Suspension Order because it contends that specified Morris & Dickson’s DEA-registered pharmacy customers have filled “unusually large” orders for oxycodone and hydrocodone. For the reasons explained below, all of the relevant factors for evaluating whether to issue a TRO favor relief here.

7. **Likelihood of Success.** Morris & Dickson is likely to succeed on the merits of its challenge to the License Suspension Order. A License Suspension Order is DEA’s most powerful enforcement sanction. It can be imposed without advance notice and without an opportunity for a hearing, and it has the potential to destroy businesses and livelihoods. License Suspension Orders are therefore reserved for addressing only the most dangerous activities of the most serious violators.

8. The caselaw and the governing statute are clear: an License Suspension Order cannot be imposed unless DEA establishes that it is necessary to prevent an imminent danger to the

public health or safety. *See* 21 U.S.C. § 824(d). Here, DEA cannot meet that burden for the following reasons.

9. Immediate suspension of the Morris & Dickson's licenses to distribute controlled substances is unnecessary to address the problem DEA alleges "unusually large" orders by the pharmacies identified in the License Suspension Order.

10. As set forth below, many of the facts alleged in the License Suspension Order are inaccurate and/or misleading. Specifically, the License Suspension Order identifies the following customers:

- a. Wallace Drug Company, Inc. d/b/a Wallace Discount Drugs
- b. Bordelon's Super-Save Pharmacy
- c. Folse Pharmacy
- d. Pharmacy Specialties Group, Inc.
- e. Dave's Pharmacy
- f. Hephzibah Pharmacy LLC
- g. The Wellness Pharmacy, Inc.
- h. Wilkinson Family Pharmacy

11. Morris & Dickson no longer does business with Wilkinson Family Pharmacy (lost its license), The Wellness Pharmacy, Inc. (closed), and Hephzibah Pharmacy LLC (no longer a customer).

12. With respect to the other customers cited in DEA's License Suspension Order:

Wallace Drug Company

DEA intentionally misrepresents notes produced by Morris & Dickson Compliance Officer Clara Guinn by omitting material facts, which if quoted in full, would clearly show that shipments

to Wallace Drug Company Inc. on January 9, 2018, were not in fact suspicious, and the potentially excessive orders were in fact returned to Morris & Dickson after shipment as a result of Ms. Guinn's due diligence.

Contrary to the DEA's statement that Morris & Dickson did not conduct any due diligence following a notation that Wallace Drug was ordering higher than normal amounts, Morris & Dickson pro-actively conducted due diligence by contacting the customer directly and obtaining a return of the drugs at issue. The full quotation below shows that Morris & Dickson Compliance officer Clara Guinn conducted due diligence regarding the potentially suspicious order by contacting the local salesman, Tommy Tingstrom, and then calling the pharmacist directly:

FW6006363 1/9/2018 Might need to check on this guy he has ordered 12 bottles of 1,000 hydrocodone/apap 10/325 item 51627 the last two days and has another order in today for 12 more, so 36 bottles of 1,000 in three days Vault

FW6006363 1/9/2018 Also got 12 of the 5mg 1,000 and 24 of the 7.5mg 1,000.....so looks like he is hitting this stuff hard!

FW6006363 1/9/2018 I contacted his salesman, Tommy T. to find out what was going on. Customer was stocking up because he had heard that Hydrocodone was in short supply, that other pharmacies were having problems getting shipments. I told Tommy to let him know that we had stock & that we did not allow customers to 'Stock Up'. I gave Tim a couple of scenarios to discuss with him. 1. What if he was audited and had to explain the excessive stock? 2. What if he were robbed and had to explain the excessive stock. Tim will also let him know we have stopped today's shipment and that I recommend that he return these items for credit & continue his normal ordering habits. Within an hour, he sent a request for a return blank. CG

The final line, "Within the hour, he sent a request for a return blank" establishes that the Wallace Drug pharmacist was requesting a return blank to return the drugs which were over-ordered.

There was no indication to the Morris & Dickson Compliance team that the pharmacist was engaging in diversion. To the contrary, the pharmacist explained, in the telephone conversation with Clara Guinn, that he was ordering extra of certain narcotics to "stock up" in

response to supply issues. Morris & Dickson's action, is a clear example of practical due diligence to address a potentially suspicious order and combat diversion. Morris & Dickson obtained a return of all excessive drugs ordered.

The full quotation of Clara Guinn's notes was provided in response to the DEA's second subpoena regarding potentially suspicious orders on March 30, 2018. The DEA's failure to include the entire quotation constitutes a material omission of fact, which if included would reasonably explain why Morris & Dickson did not regard this order as suspicious, and would also establish that Morris & Dickson conducted the required due diligence.

Bordelon's Super-Save Pharmacy

DEA cites stale statistics. In the last six (6) months, Morris & Dickson's shipments of opioids to this pharmacy have reduced by 14%.

Folse Pharmacy

DEA cites stale statistics. In the last six (6) months, Morris & Dickson's shipments of opioids to this pharmacy have reduced by 33%.

Dave's Pharmacy

DEA cites stale statistics. In the last six (6) months, Morris & Dickson's shipments of opioids to this pharmacy have reduced by 6%.

13. In addition to the above, Morris & Dickson maintains a vigorous and robust anti-diversion system. Indeed, Morris & Dickson's anti-diversion system, in important aspects, is more comprehensive than DEA's own enforcement efforts. The quantity of opioids shipped by Morris & Dickson to pharmacies has significantly decreased in recent years. Attached as **Exhibit B** is a chart showing the reduction in quantities of opioids shipped to each state in the last two years. These reductions show that Morris & Dickson's systems are indeed working.

14. **More importantly, Morris & Dickson agrees to immediately terminate shipments of controlled substances to all customers identified in the License Suspension Order until such time as the Court holds a hearing and and/or the License Suspension Order is lifted.**

15. It is undisputed that Morris & Dickson has distributed controlled substances only to DEA-registered pharmacies and health care facilities. DEA does not allege that Morris & Dickson has sold or distributed a single dose of oxycodone or hydrocodone outside this closed system of authorized distribution. The sole bases for DEA's License Suspension Order against the Morris & Dickson is its allegations concerning "unusually large" orders and diversion of drugs.

16. The License Suspension Order will not halt or reduce diversion of controlled substances by anyone and, therefore, does not diminish the "imminent danger" that DEA alleges. The customers of Morris & Dickson that retain DEA registrations will continue to receive controlled substances from other distributors. In fact, because these distributors may not have the same robust anti-diversion controls as Morris & Dickson does, the License Suspension Order likely will exacerbate the risk of diversion, if it has any effect at all.

14. **Immediate Irreparable Harm.** A TRO is also necessary to prevent irreparable harm to Morris & Dickson and its customers. Morris & Dickson has one distribution facility in Shreveport, Louisiana. From that facility, Morris & Dickson supplies *all* of its customers—hundreds of hospitals, pharmacies, alternative care providers, and other health care providers. Morris & Dickson's customers require prompt delivery of controlled substances for thousands of oncology, surgery, urgent care, emergency room, and hospice care patients.

15. In the absence of a TRO, DEA's actions will cause serious disruption in the supply chain for controlled substances, resulting in delays in treatment for legitimate patients already facing drug shortages. Make no mistake—this is a life and death situation. Morris & Dickson services

approximately 40% of the hospital drug market in Louisiana and Texas alone. If Morris & Dickson cannot ship needed medications to these hospitals, these hospitals may face immediate drug shortages. Due to exclusive supply arrangements at some of these facilities, the hospitals and alternate care facilities will not have a source in the short term to obtain clinically necessary and life-saving medications outside of the Morris & Dickson supply chain.

16. Many of these of these customers are Louisiana and Texas Hospitals including University Health Center, Shreveport, Willis Knighton Health Systems, Shreveport, Children's Hospital, Touro Infirmary, University Medical Center, and Jefferson Medical Center in New Orleans, Baton Rouge General Hospital, Baton Rouge, LA, Lafayette General Medical Center, Children's Hospital in New Orleans and Dallas, Texas Children's Hospital, Houston, University of Texas Southwest Medical Center, Dallas, Methodist Hospital System, Houston and many others. Hospital customers are dependent on receiving next day and same day shipments from Morris & Dickson. In addition, in urgent situations, *i.e.* where the hospital emergency room had a sudden shortage in a particular medication, the Shreveport distribution center could provide an emergency shipment to that customer in as little as three to six (6) hours. If this suspension of licensing is enforced, Morris & Dickson could not make emergency shipments to any hospitals in Louisiana, Texas, or any other of the 17 states it serves. Due to Morris & Dickson's single distribution point model, it has no alternate method to get shipments to hospitals, pharmacies or nursing homes.

17. Any delays in delivery of shipments by Morris & Dickson to hospital customers will cause delays in treatment of patients, including seriously ill or terminally ill patients in need of medication. A hospital's needs for controlled substances are ever-changing and unpredictable. Most hospitals do not store large volumes of controlled substances but rather have "just-in-time" inventory levels. Therefore, many hospitals place daily or even more urgent orders with Morris &

Dickson as their needs change, i.e. as patients present themselves in the emergency room with unforeseen injuries and illnesses. These hospitals will not receive deliveries of any kind, including rush deliveries, if the suspension is enforced.

18. If a hospital fails to receive timely orders of controlled substances, patients will experience delays in treatment, and hospitals will experience immediate drug shortages. Unlike outpatients, hospital inpatients cannot seek relief from a neighboring pharmacy when the hospital is experiencing delays or shortages in pain medications. Thus, when a hospital experiences a shortage, its only choices are to delay treatment with pain medication, to administer a less effective treatment, or to delay other therapies, such as surgery, until the hospital receives an adequate supply. With no ability to ship controlled drugs, hospitals within Morris & Dickson's distribution network will be denied access to critically necessary, and lifesaving medication.

19. If remedy is not granted to Morris & Dickson to stay the license suspension, Morris & Dickson Hospital, pharmacy and nursing home customers will have to contract with a new DEA licensed wholesaler. The transition process between vendors, during which the wholesaler procures an adequate supply to meet the demands of the hospital, takes no less than two weeks and up to one month. In the meantime, hospitals currently supplied by Morris & Dickson will face drug shortages.

20. This also would also cause severe and irreparable harm to Morris & Dickson. The company would suffer significant damage to its business reputation and loss of customer goodwill. Some customers will likely stop doing business with Morris & Dickson and never return. Additionally, the License Suspension Order will cause Morris & Dickson to lose significant revenue that it could never recover. Morris & Dickson has no adequate remedy at law if this Court does not immediately enjoin DEA from enforcement of the License Suspension Order.

21. **Balance of Hardships.** The balance of hardships also supports issuing a TRO. As explained above, there is no imminent danger to the public health that requires an immediate suspension of Morris & Dickson's licenses. Also, in the same notice as the License Suspension Order, DEA served an Order to Show Cause, initiating a DEA administrative process for considering whether revocation of the Morris & Dickson's registration is appropriate. *See* Ex. A. In either case, DEA would be required to give advance notice to Morris & Dickson and provide it an opportunity to respond to the allegations against it. But in the absence of an imminent danger to the public, there is no need or legal basis to deprive Morris & Dickson of the process afforded by law.

22. **Public Interest.** Finally, the public interest weighs heavily in favor of granting a TRO. As noted above, the License Suspension Order is not necessary to prevent any imminent harm to the public. By delaying shipments, however, a TRO would cause injury to the numerous patients that depend on Morris & Dickson for an uninterrupted supply of medications for their legitimate medical needs. Accordingly, Morris & Dickson respectfully requests that the Court temporarily enjoin enforcement of the License Suspension Order until the Court can rule on a motion for a preliminary injunction to be filed by Morris & Dickson.

23. This case is nearly identical to one involving Cardinal Health, another distributor, in 2012. *See Exhibits C, and C-1*, attached hereto, Order and Memorandum of Cardinal Health. There, the federal district court granted Cardinal Health's temporary restraining order and enjoined DEA's License Suspension Order. For the same reasons, this Court should grant Morris & Dickson's Motion.

Conclusion

For the foregoing reasons, Morris & Dickson requests that this Court issue a TRO that prevents DEA from enforcing the License Suspension Order pending the resolution of a motion for a preliminary injunction (or other judicial proceedings).

Respectfully submitted,

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Since January 1, 2007, Morris & Dickson has suspended shipment of controlled substances to more than 375 customers, including more than 180 pharmacies in Florida, that it believed posed an unreasonable risk of diversion. *Id.*, r 23. In the last three months alone, Morris & Dickson has suspended shipments of controlled substances to 30 DEA-registered pharmacies in Florida. *Id.*, r 43. In 2011, Morris & Dickson also rejected, at the initial review stage, applications of 55 pharmacies seeking to obtain controlled substances. *Id.*, r 11. In many respects, Morris & Dickson's compliance program is more stringent than DEA's: a large percentage of pharmacies suspended by Morris & Dickson still retain their DEA registration. Since January 1, 2009, of the 315 pharmacies suspended by Morris & Dickson nationwide, 216 maintain an active DEA registration today, even though Morris & Dickson notified DEA about each termination. *Id.*, r 23. During the same time period, Morris & Dickson suspended controlled substance shipments to more than 149 pharmacies in Florida, but 113 still have registrations today. *Id.* Indeed, a federal court in Oklahoma once questioned Morris & Dickson's decision to terminate a pharmacy, in part because there had been no "adverse regulatory action against it." *Apothecaryx, LLC v. Morris & Dickson 110, Inc.*, No. 5:07-cv-01399-D (W.D. Okla. Dec. 17, 2007) (temporary restraining order).

Morris & Dickson continues to strive to improve its systems. For instance, it recently began coordinating its anti-diversion efforts with oxycodone manufacturer Mallinckrodt, Inc. *Id.*, r-r 39-40. In fall 2011, Mallinckrodt shared information (previously unknown to Morris & Dickson) about purchases of controlled substances by specific Florida pharmacies through multiple wholesalers. *Id.* That information prompted Morris & Dickson to suspend sales of controlled substances to certain customers that

presented an unreasonable risk of

diversion. *Id.*, -r 40. Morris & Dickson intends to continue cooperation with Mallinckrodt. *Id.*

DEA has even better data than Mallinckrodt because *all* distributors are required to regularly report to DEA their total distributions to pharmacies of Schedule II drugs and narcotic Schedule III drugs through DEA's "ARCOS" system.⁴ DEA itself recognizes the value of data unavailable to a single distributor. It has told distributors that one indication of diversion by a pharmacy is whether it is "[o]rdering the same controlled substances from multiple distributors." Letter from Deputy Assistant Administrator Joseph T. Rannazzisi to Morris & Dickson at 3 (Feb. 7, 2007) (Ex. B). Yet DEA has declined to provide information about pharmacies' purchases in response to frequent requests by Morris & Dickson and the wholesale industry. Mone Decl., -r, -r 37-38.⁵ In addition, just over three months ago, Morris & Dickson requested that DEA inform it "of the identity of any Morris & Dickson customer that the agency has determined is engaged in the diversion of controlled substances." Letter from Craig Morford, Chief Legal and Compliance Officer, to Adm'r Michele M. Leonhart (Oct. 27, 2011) (Ex. C). In that letter, Morris & Dickson made clear to DEA that it would "immediately cease distribution of controlled substances to any customer that DEA so identifies." *Id.* Morris & Dickson subsequently reiterated its request for information about any of its "customers that the DEA believes are likely engaged in illegal activity or diversion." E-mail from Jamie Gorelick to Chief Counsel Wendy H. Goggin (Dec. 22, 2011) (Ex. D). DEA rejected Morris & Dickson's requests. Mone Decl., -r 38.

⁴ 21 U.S.C. § 827(d); 21 C.F.R. § 1304.33.

⁵ The Healthcare Distribution Management Association ("HDMA"), which represents the interests of wholesale distributors like Morris & Dickson, requested this data, called

"ARCOS" data, in meetings with DEA in February 2009 and December 2010, and in letters in July 2010 and June 2011. *See* Mone Decl. ,r 37; Letter from John M. Gray, President of Healthcare Distribution Management Ass'n, to Administrator Michele M. Leonhart, p. 10 (June 1, 2011). (Ex. E); HDMA, Summary of the DEA-HDMA Meeting Held on Dec. 7, 2010, p. 2 (Ex. F).

Even without DEA's assistance, Morris & Dickson continues to combat potential oxycodone diversion by its customers. Because of reports of oxycodone abuse in Florida, in November 2010 Morris & Dickson sent teams of compliance investigators and pharmacists to gather data on and perform inspections of 53 of its largest retail independent pharmacy customers in Florida. *Id.*³³. This investigation resulted in suspension of shipments of controlled substances to several of the 77 Florida pharmacies to which Morris & Dickson had temporarily halted such sales in the last three years. *Id.*

V. The February 2, 2012 Immediate Suspension Order

Despite Morris & Dickson's extensive compliance program, on February 2, 2012, DEA issued the License Suspension Order. DEA then served the License Suspension Order on February 3, 2012, immediately suspending the Morris & Dickson's controlled substances registration. Ex. A. In the same notice as the License Suspension Order, the DEA also served an Order to Show Cause initiating DEA administrative procedures to revoke the Morris & Dickson's controlled substances registration. *Id.*

The License Suspension Order alleges that continued registration of the Morris & Dickson presents an imminent danger to the public health or safety because, according to the License Suspension Order, Morris & Dickson's compliance program is ineffective. *See id.* at 2-3. The sole basis for this assertion is DEA's contention, that 4 pharmacy customers of Morris & Dickson have distributed oxycodone for illegitimate uses. *See id.* at 2. The License Suspension Order does not allege that Morris & Dickson itself has distributed controlled substances to any entity not permitted to purchase them. Rather, it alleges that Morris & Dickson should have known that 4 of its pharmacy customers were filling prescriptions for

allegedly illegitimate purposes. *Id.* at 3.

Morris & Dickson already suspended distributions to the two named independent pharmacies months ago (one on September 26, 2011 and the other on October 5, 2011), and has temporarily suspended distributions to the two named CVS pharmacies while the court

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considers this motion. *Id.* 'lf'lf48, 55.

VI. The License Suspension Order's Effects on Morris & Dickson

If the License Suspension Order is not enjoined, Morris & Dickson would be forced to reroute controlled substances previously distributed from its Lakeland distribution center to its distribution centers in Greensboro, North Carolina; Madison, Mississippi; and Denver, Colorado. Giacomini Decl. '1'1'17-9. This rerouting would cause delays in the receipt of controlled substances by Morris & Dickson's Florida customers. *Id.* '1'1'18-9. Those customers, who typically receive next day shipments from the Morris & Dickson, would have to wait up to three days for shipments from the Denver facility and two days for shipments from other facilities. *Id.* '1'1'16, 8-9.

The License Suspension Order's effects would be severe. The Morris & Dickson's primary customers include hospitals, nursing homes, retail independent pharmacies, and urgent care centers that place orders on a daily basis. *Id.* ¶ 5. Because there is currently a shortage of certain controlled substances in the United States, those customers will not always be able to secure needed medications from secondary vendors. *Id.* 'lf'lf15-16. Indeed, even before the License Suspension Order was issued, it was difficult for critically ill patients to obtain the pain medication they needed. See David S. Craig, *Cancer Patients Denied Needed Pain Treatment*, St. Petersburg Times, Dec. 8, 2011, at 11 A (Ex. G) ("As Florida officials have cracked down on 'pill

mills '-medical clinics that illegally and unethically distribute pain medications while masquerading as legitimate pain management clinics-the effort has hindered the legitimate use of these medications. As a result, cancer patients are finding it harder to get the pain medications they need."). For Morris & Dickson's customers, disruptions in supply can equate to disruption in patient care and delays in treatment for seriously ill or terminal patients. Giacomini Decl. '1110.

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As a result of the delays, some Lakeland facility customers will likely leave Cardinal

Health permanently for other distributors-as occurred in the wake of the 2007 License Suspension Order. *Id.*

20-22. Most customers prefer to order pharmaceuticals from a single large distributor because it is not cost effective to order controlled substances and non-controlled substances from different distributors. *Id.* 20. Some portion of the Morris & Dickson's customers thus

is expected to take their entire pharmaceutical business to Morris & Dickson's competitors.

Id.; see also *id.* 21-22.

I. Morris & Dickson Is Likely To Succeed On The Merits

Morris & Dickson is likely to succeed on the merits because DEA has not met the strict standard for suspending a registrant without notice and an opportunity to be heard, its decision is otherwise arbitrary and capricious, and DEA has deprived Morris & Dickson of due process.

A. DEA Has Failed To Establish Imminent Danger To Public Health Or Safety

Morris & Dickson's challenge to the License Suspension Order is likely to succeed because DEA cannot establish that suspension of the Morris & Dickson's registration is necessary to prevent an imminent danger to the public health or safety. Orders by DEA affecting a company's registration are subject to review under the standards set forth in the APA. *Moral! v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) (vacating DEA decision to revoke physician's DEA registration); *Wedgewood Village Pharmacy v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007) (vacating DEA decision to revoke pharmacy's DEA registration). Review of an order for immediate suspension under § 824(d) may be sought in district court without awaiting further action by DEA. *See Novelty Distribs., Inc. v. Leonhart*, 562 F. Supp. 2d 20, 24-28 (D.D.C. 2008); *Norman Bridge*, 529 F.2d at 828-29; *Neil Laboratories, Inc. v. Ashcroft*, 217 F. Supp. 2d 80, 84 n.6 (D.D.C. 2002); *see also* 21 U.S.C. § 824(d) (providing that an License Suspension Order can be "dissolved by a court of competent jurisdiction").

As noted above, an License Suspension Order may be issued only when

necessary to protect the public health or safety from an "imminent danger." 21 U.S.C. § 824(d); *see Norman Bridge*, 529 F.2d at 828; *PRSI Acquisition Group, LLC v. Ashcroft*, No. 02-cv-1020, slip op. at 2 (D.D.C. May 30, 2002) (order granting preliminary injunction) ("DEA's finding of imminent danger was arbitrary and capricious") (Ex. H); *Bates Drug Stores*,

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Inc. v. Holder, No. CV-11-0167-EFS, 2011 WL 1750066, at *4 (E.D. Wash. May 6, 2011) (enjoining Immediate Suspension Order under 21 U.S.C. § 824(d)). This heightened standard is necessary to ensure that registrants are not deprived of their registrations without due process of law. As explained below in § I(C), revoking a registration without notice and an opportunity to be heard can be justified-if ever- only in extraordinary circumstances. In order to avoid raising constitutional concerns, § 824(d)'s "imminent danger" standard should be interpreted to require that DEA carry the heavy burden of showing that immediate suspension is necessary to prevent a concrete and imminent threat to public safety that cannot be avoided through less drastic measures. *See Edward J DeBartolo Corp. v. Florida Gulf Coast Bldg. & Const. Trades Council*, 485 U.S. 568, 575 (1988). Here, continued registration of the Morris & Dickson presents no imminent danger to the public health for multiple reasons.

1. Morris & Dickson Has Already Suspended Sales To The Pharmacies Identified In The License Suspension Order And Stands Ready To Terminate Sales To Any Other Pharmacy DEA Believes Poses A Risk Of Diversion

Immediate suspension of Morris & Dickson's registration is not necessary to prevent the harm that DEA has identified-dispensing of controlled substances for illegitimate uses by four pharmacies identified in the License Suspension Order. Morris & Dickson already suspended distributions to the two named independent pharmacies months ago, and has temporarily suspended distributions to the two named CVS

pharmacies while the court considers this motion. *See* Mone Decl. 48-49, 55-56. The suspension of these pharmacies eliminates any arguable danger to the public health. Indeed, similar corrective action caused this Court to preliminarily enjoin an License Suspension Order in *PRSI Acquisition*. In that case, the Court found that any imminent danger had been resolved because the employee whose conduct gave rise to

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the License Suspension Order had been terminated. *PRSI Acquisition*, No. 02-cv-1020, at 2 (Ex. H).

Moreover, Morris & Dickson stands ready and willing to cease distributions to any customer that poses an undue risk of diversion. As noted above, *see supra* at 2; Ex. D, Morris & Dickson has made clear to DEA that it will suspend controlled substance shipments to any pharmacy the agency identifies as posing an undue risk of diversion. Such a suspension would eliminate any risk of harm to public health asserted by DEA in the License Suspension Order.

2. Morris & Dickson Has An Effective Anti-Diversion Program

Morris & Dickson's continued registration also poses no imminent danger to the public health because the company maintains a robust anti-diversion system, described by DEA's own inspectors as one of the best among wholesale drug distributors nationwide, *see* Mone Decl. ¶ 29. As noted above, over 40 Morris & Dickson employees are dedicated to compliance. *See supra* at 7.⁶ Morris & Dickson establishes and reviews ordering thresholds for its customers, monitors its customers' purchases of controlled substances, and investigates potentially suspicious orders. *See id.* As explained above, DEA has reviewed Morris & Dickson's SOM system and has been provided with information about updates to the system since 2009 yet has never previously raised any significant concerns about the system. *See* Mone Decl. ¶¶ 28-29, 35-36.

The DEA now contends in the License Suspension Order that Morris & Dickson's

SOM program is ineffective. But the License Suspension Order provides no basis for this conclusion. DEA cannot dispute the fact that Morris & Dickson already suspended distribution to the two named independent

⁶ Morris & Dickson's commitment to combating diversion is evident from the leadership team it assembled to run its SOM program. In May 2008, Morris & Dickson hired former acting Deputy Attorney General Craig Morford to serve as Chief Legal and Compliance Officer. Mone Decl. ¶ 3. In December 2007, Morris & Dickson hired Michael Mone as Vice President for Supply Chain Integrity. *See id.* Mr. Mone, both a lawyer and a pharmacist, has extensive experience with pharmacy regulation and anti-diversion efforts. *See id.* ¶ 2.

pharmacies months ago, and has temporarily suspended distributions to the two named CVS pharmacies while the court considers this motion. DEA relies primarily on the volume of controlled substances ordered by the pharmacies. But the agency itself recently held that the volume of controlled substances alone, even in an area notorious for oxycodone abuse, was inconclusive evidence of diversion. *Carlos Gonzalez, MD.*, 76 Fed. Reg. 63,118, 63,138 (DEA Oct. 11, 2011). High volumes of controlled substance sales to a pharmacy might mean only that the pharmacy serves a higher than average volume of legitimate acute pain patients (for example, if a pharmacy is located near an oncology clinic or a hospice, or has a higher than average proportion of elderly customers). *Cf id.* ("[T]here are a host of factors that could account for ... the Respondent's level of controlled substance prescribing").

To determine whether high sales volumes are suspicious, a distributor must consider other information. DEA consider a multitude of factors relating to public health needs in determining the appropriate quotas for the amount of controlled substances that can be manufactured in the United States.⁷ Morris & Dickson and other distributors-which like DEA must also fulfill public health obligations-are justified in considering similar factors in setting thresholds for their purchasers. While DEA criticizes the effectiveness of Morris & Dickson's SOM program in detecting diversion, the difficulty of determining whether a facially valid prescription is being filled for

illegitimate purposes has also been recognized by DEA. As Joseph Rannazzisi, DEA's

Deputy Assistant Administrator in

charge of the Office of Diversion Control, has publicly stated, "[a] tremendous challenge for

⁷ See *National Drug Threat Assessment, 2010*, U.S. Department of Justice, National Drug Intelligence Center, Feb. 2010, available at <http://www.justice.gov/ndic/pubs38/38661/rx.htm> (factors supporting quota increases include "more aggressive pain treatment, new and different indications for legitimate medical use, the increase in the average age of the citizenry, new delivery methods and formulations for opioid pain relievers, new product development, and exportation").

law enforcement when dealing with pharmaceutical controlled substances is often distinguishing among legitimate medical uses and illegal uses."⁸ DEA, as a law enforcement and regulatory agency, has far more potent and comprehensive investigative tools than does a wholesale distributor like Morris & Dickson. As difficult as it is for DEA to distinguish between legitimate and illegal uses, it is a much more challenging task for wholesalers that distribute to DEA-registered pharmacies to determine whether prescriptions written by DEA-registered doctors are actually being diverted to illegitimate uses.

Here, Morris & Dickson monitored and investigated orders placed by both the 2 retail independent pharmacies and the 2 CVS pharmacies named in the License Suspension Order and formed reasonable conclusions that continued sales to them were appropriate based on the information available at the time. Mone Decl. ¶¶ 50-53, 57.

a. The Retail Independent Pharmacies

Morris & Dickson's distribution of controlled substances to the 2 retail independent pharmacies named in the License Suspension Order is no basis for an immediate suspension under § 824(d). Morris & Dickson makes decisions to distribute controlled substances to a retail independent pharmacy based on myriad factors. It considers (among other things) a pharmacy's size, history of dispensing, and location (including whether hospitals, pain clinics, orthopedic clinics, or hospices are nearby). *Id.* ¶¶ 16, 20. The information available to Morris & Dickson about a pharmacy's dispensing practices, however, is limited. Unlike DEA and pharmacists, Morris &

Dickson investigators cannot obtain individual patients' prescriptions to determine whether they were issued for a legitimate medical purpose. *Id.*, ¶ 26.

⁸ *DEA: Working to Halt the Diversion and Abuse of Prescription Drugs* at 2, ONDCP Update Volume 2, Issue 2, Feb. 2011; available at http://www.whitehouse.gov/sites/default/files/ondcp/newsletters/ondcp_update_february_2011.pdf.

In this case, Morris & Dickson sent an investigator to every retail independent pharmacy named in the License Suspension Order (repeatedly, for some pharmacies) long before learning of DEA's specific concerns. *Id.* '1'1!51-53. Based on the results of those investigations and the information available to it, Morris & Dickson investigators concluded that continued shipment to those pharmacies was reasonable. *Id.* Detailed descriptions of Morris & Dickson's consideration of each of the retail independent pharmacies named in the License Suspension Order are set forth in the Declaration of Michael Mom. *See* MomS Decl. '1'1!43-44. As explained in that declaration, Morris & Dickson considered precisely the kinds of factors that DEA endorsed in *Gonzalez* and elsewhere to detect diversion: the specialties and credentials of prescribing practitioners; volumes of certain controlled substances believed to be indicative of likely diversion; percentage of cash transactions for those medications; proximity of medical establishments with high volumes of patients with legitimate need for controlled substances; percentages of controlled substances to overall prescription drugs ordered by the pharmacy; and others. Accordingly, Morris & Dickson's past distributions of controlled substances to these pharmacies is no basis for concluding that Morris & Dickson's controls are ineffective, especially where those controls have led to the suspension of almost 150 pharmacies since January 2009.

b. The CVS Pharmacies

Morris & Dickson's distribution to 2 CVS pharmacies similarly provides no basis for the License Suspension Order. Any diversion of oxycodone by these pharmacies

cannot be attributed to a lack of diligence by Morris & Dickson. The company's anti-diversion personnel work in cooperation with CVS, a large chain of retail pharmacies (about 7,000 nationwide) that sell prescription drugs, over-the-counter drugs, and other retail goods. Mone Decl. 'Ill 0. As it does with independent pharmacies, Morris & Dickson sets order thresholds for CVS and reviews orders

for controlled substances that exceed the thresholds. *Id.* 58. Morris & Dickson held and investigated 1,690 orders from CVS pharmacies in the first ten months of 2011. *Id.* 59.

When Morris & Dickson identified potentially unusual oxycodone-ordering patterns in the fall of 2010 at the CVS pharmacies identified in the License Suspension Order (and others), it requested that CVS investigate those orders. *Id.* 60. CVS compliance personnel conducted what appeared to be adequate investigations at the relevant pharmacies, and the findings from those investigations were reported to Morris & Dickson. *Id.* With respect to the two Sanford stores identified in the License Suspension Order, which Morris & Dickson identified to CVS first, CVS reported that it had investigated the matter and that the orders of oxycodone were appropriate for the activity at those stores. *Id.* Subsequently, CVS sent Morris & Dickson a letter outlining its investigation of additional Florida CVS stores that Morris & Dickson had identified. *Id.*; Letter from Brian E. Whalen to Paul Farley (Jan. 6, 2011) (Ex. M4). The letter indicated that teams of CVS Pharmacy SupervLicense Suspension Orders and Regional Loss Prevention Managers visited the stores, interviewed pharmacy staff, and reviewed controlled substance ordering, receiving and dispensing procedures, controlled substance records and reports, and security. Ex. M4. The teams reportedly "found no evidence of controlled substance diversion or significant losses." *Id.* The letter noted that CVS was "confident that pharmacists and their staffs at these pharmacies understand how to minimize the risk of

dispensing controlled substances, particularly opioids for pain management, for non-legitimate purposes." *Id.* Finally, it assured Morris & Dickson that CVS was "comfortable with Cardinal continuing to ship controlled substances to these pharmacies." Based on these reports, Morris & Dickson reasonably concluded that continued distributions to these stores were appropriate. Mone Decl. 57.

Morris & Dickson had good reason to believe that the CVS anti-diversion program was reliable. Large chains like CVS have the resources to investigate potential diversion, and chain pharmacists do not share directly in any profits from diversion.

Id. 10, 61. The

head of Morris & Dickson's compliance department, Michael Mone, had contacts with CVS pharmacy officials at numerous levels whom he reasonably believed to be diligent professionals of high integrity and good judgment. *Id.* 61. The response to Morris & Dickson's inquiries about the Florida stores in 2010 appeared credible.

Id. 60; Ex. M4. Indeed, Morris & Dickson had previously informed DEA in 2009 that it relied on CVS compliance personnel to conduct these investigations, and DEA never expressed any objection. Mone Decl. 29. In these circumstances, an immediate suspension simply

cannot be justified. *See Norman Bridge*, 529 F.2d at 829 (DEA's failure to act on violation for 7 months means violation does not pose an imminent danger to public health and safety). Focusing almost entirely on volume alone, DEA alleges in the License Suspension Order that the Lakeland facility should not have shipped 5 million doses of oxycodone in a 48-month period to a CVS pharmacy located in Sanford, Florida. *See* Ex. A at 2. The agency claims that the amount shipped was higher than the national average. *Id.* But the volume of oxycodone distributed by Morris & Dickson to this CVS pharmacy appeared reasonable in light of information available to Morris & Dickson about the pharmacy's size, location, and operating hours.

Mone Decl. 54. The pharmacy is open seven days a week and is much larger than most retail independent pharmacies. *Id.* The amount of oxycodone Morris & Dickson distributed to this CVS store was sufficient to fill only about 33 prescriptions per day, as estimated by Mr. Mone. *Id.* Because of the large volume of prescriptions typically filled at large CVS stores, Mr. Mone reasonably believed that the relatively small volume of oxycodone prescriptions

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filled on a daily basis did not place this store in the same category as the "pill mills" that DEA has publicly warned distributors about. *Id.*

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DEA has thus failed to show that Morris & Dickson's SOM program is ineffective, either with respect to retail independent pharmacies or CVS pharmacies. To the extent, however, that DEA identifies any specific flaws in its SOM program, Morris & Dickson stands willing and able to remedy the situation immediately.

3. DEA Has Not Alleged That Morris & Dickson Distributed Controlled Substances Outside The Closed System Of Distribution

Suspension of Morris & Dickson's Morris & Dickson is not necessary to address the danger DEA alleges-that certain pharmacies have been improperly filling illegitimate oxycodone prescriptions. The CSA established "a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of controlled substances. *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). Here, DEA has not alleged Morris & Dickson or its employees illicitly sold or otherwise distributed controlled substances outside the closed system of distribution. In fact, Morris & Dickson distributes controlled substances only to customers with active, valid DEA registrations. Mone Decl.

4. DEA granted registrations to those customers because the agency determined that it was in the public interest to do so.⁹ Yet, DEA now seeks to take the extraordinary step of suspending Morris & Dickson's registration, despite the fact that every

pharmacy to which

Morris & Dickson sold controlled substances was expressly authorized by DEA to

purchase and resell those drugs.

⁹ The Attorney General, through DEA, may deny an application for registration if he determines that the issuance of such registration "would be inconsistent with the public interest." 21 U.S.C. § 823(f).

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4. Suspending Lakeland Will Not Prevent Diversion By Third Parties

Suspension of Morris & Dickson's Morris & Dickson will not address the harm DEA alleges because it will not prevent pharmacies filling illegitimate prescriptions from simply obtaining controlled substances from another distributor. The "imminent danger" to public health or safety alleged by DEA is distribution of controlled substances to pharmacies that fill prescriptions that were not issued for a legitimate medical purpose. If this Court allows the License Suspension Order to stand, however, there is no evidence that the practitioners who prescribe, and the pharmacies that dispense, the controlled substances that concern DEA would alter their practices at all. Absent further action from DEA or from the pharmacies filling the prescriptions that these practitioners write (circumstances entirely outside of Morris & Dickson's control), the same practitioners would doubtless continue to prescribe the same controlled substances to the same patients. Many of the pharmacies with DEA registrations would merely turn to other distribution sources to obtain controlled substances, suppliers that do not have anti-diversion programs as robust as Morris & Dickson's, *see* Mone Decl.

35 (DEA official characterized Morris & Dickson's monitoring program as "going above and

beyond"). As a result, DEA cannot show that issuance of the License Suspension Order would prevent an imminent danger to public health and safety, a finding mandated by the CSA for the issuance of an License Suspension Order.

Indeed, an License Suspension Order is particularly inappropriate since
DEA has known about the

Morris & Dickson's sales of oxycodone to these pharmacies-and to all other
customers-for many months. One of Morris & Dickson's obligations under the MOA is
to provide DEA, on

a monthly basis, a report of all sales transactions of controlled substances. *See* Mone
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,r 27; MOA art. II(1)(b) (Ex. MI). If DEA believed Morris & Dickson's sales to
DEA-

registered pharmacies was creating an imminent danger to the public, it should have acted
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the time it learned of those sales, not months later. DEA's delay in imposing the License Suspension Order alone is reason enough to grant the TRO.

B. Issuance Of The License Suspension Order Was Arbitrary And Capricious, In Violation Of The APA

In addition to failing to meet the "imminent danger" standard of § 824(d), the License Suspension Order is arbitrary and capricious. Under the APA, agency action must be set aside if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with applicable law. *See* 5

U.S.C. § 706; *Morall*, 412 F.3d at 177. Here, DEA's License Suspension Order is arbitrary and capricious

because DEA failed to consider alternative actions more reasonably tailored to addressing its diversion concerns as well as the impact that its License Suspension Order would have on the public health. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983); *International Ladies Garment Workers' Union v. Donovan*, 722 F.2d 795, 817 (1983) ("[I]t is absolutely clear from decisions by the Supreme Court and this court that such an artificial narrowing of options is antithetical to reasoned decisionmaking[.]").

First, DEA failed to consider other, more tailored means of addressing the oxycodone abuse problem in Florida, including, providing information to Morris & Dickson and other distributors that will help them to identify divellers of controlled substances. Even more directly, instead of revoking a distributor's registration, DEA could address diversion, without affecting the distribution of controlled substances to

legitimate patients, by suspending or revoking DEA registrations of practitioners writing oxycodone prescriptions for illicit purposes and of pharmacies that fill those prescriptions. A pharmacist is required by law to investigate whether each prescription it fills is issued for a legitimate medical purpose, an investigation that Morris & Dickson, as a wholesaler, cannot conduct.¹⁰ 21 C.F.R.

¹⁰ As a distributor, Morris & Dickson has limited information available to detect diversion.

§ 1306.04(a) (2011); *see also* Pharmacist's Manual, DEA Office of Diversion Control, Section IX, available at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_content.htm #9 ("To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section," including that the prescription "must be issued for a legitimate medical purpose").

Second, despite the fact that DEA has stated that its role is to further the CSA's purpose to "prevent, detect, and eliminate the diversion of controlled substances ... into the illicit market while ensuring a sufficient supply of controlled substances ... for legitimate medical ... purposes," 76 Fed. Reg. at 39,318 (July 6, 2011), DEA has failed to consider the drastic-and unnecessary-consequences that the License Suspension Order will have on legitimate patients and health care institutions. The License Suspension Order precludes shipment of *all* controlled substances, not just oxycodone. But there is nothing in the record establishing any potential harm to the public health as the result of sales of drugs other than oxycodone. Moreover, the License Suspension Order will cause the Morris & Dickson's Florida hospital customers to experience delays of *at least* twenty four hours in receipt of their controlled substances. Giacomini Decl. ¶¶ 8-9. Hospitals generally do not keep a large inventory of even critical medicines on hand; rather, they depend upon prompt delivery from wholesalers. *See id.* ¶ 11. Prior to

DEA's License Suspension Order, these shipments could have been made in as little as 3-6 hours in emergency situations. *Id.*, ¶ 6. Many of these medications are in short supply and thus many of Morris & Dickson's customers cannot look initially to secondary vendors. *Id.*, ¶¶ 15-16. Accordingly, the License Suspension Order

For example, pursuant to the limitations of state law and the federal Health Insurance Portability and Accountability Act ("HIPAA"), Morris & Dickson may not obtain patient-identifiable information from pharmacies or physicians. 42 U.S.C. § 1320d. This information is, however, available to pharmacists, physicians, and DEA as a regulatory and law enforcement agency.

would result in patients served by the Morris & Dickson's Florida customers experiencing delays in treatment. *Id.* 10-13, 14-15, 19.

Finally, DEA has failed to consider the implications of rendering ineffective Morris & Dickson's anti-diversion efforts in Florida. DEA investigators have regarded Morris & Dickson's anti-diversion program as one of the best among wholesale drug distributors nationwide. Mone Decl. 29. Because pharmacies with DEA registrations might have to obtain controlled substances from smaller, regional wholesalers with less developed anti-diversion capabilities, the risk of diversion is even greater in Florida because of the License Suspension Order. DEA's failure to consider these consequences in issuing its License Suspension Order renders its decision arbitrary and capricious.

C. The License Suspension Order Violated Morris & Dickson's Due Process Rights

DEA's issuance of an immediate suspension-without prior notice or an opportunity for Morris & Dickson to be heard-also violated Morris & Dickson's Fifth Amendment Right to Due Process. For Morris & Dickson to succeed in a due process claim, the company must demonstrate that "(1) it has a protected interest, (2) the government deprived it of this interest, and (3) the deprivation occurred without proper procedural protections." *PDK Labs Inc. v. Reno*, 134 F. Supp. 2d 24, 32 (D.D.C. 2001) (Fifth Amendment protects plaintiff's liberty interests, which include ability to import and manufacture pseudoephedrine, a "listed chemical" regulated by DEA). Morris & Dickson easily meets these three criteria.

Morris & Dickson has a valid property interest in its DEA registration to receive and distribute controlled substances. *See Harline v. DEA*, 148 F.3d. 1199, 1204 (10th Cir. 1998) (physician's property interest in his DEA registration entitles him to a hearing before his registration could be suspended or revoked for alleged improper dispensing of controlled substances); *Novelty Distributors*, 562 F. Supp. 2d at 30 (noting "the property

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interests of distributors" in their registrations). Deprivation of a protected interest without an opportunity for a hearing violates due process except in "rare and extraordinary situations." *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 570 n.7 (1972).

This case does not present an "extraordinary situation[]" where some valid governmental interest is at stake that justifies postponing the hearing until after the event," *Boddie v. Connecticut*, 401 U.S. 371, 379 (1971); *Nat'l Council of Resistance of Iran v. Dep't of State*, 251 F.3d 192,208 (D.C. Cir. 2001) (government must "make a showing of particularized need" in order to dispense with pre-deprivation process). As demonstrated above, DEA has failed to establish that Morris & Dickson's continued registration poses an imminent danger to the public health or safety; indeed, if anything, suspension of that registration will harm the public health. Absent an imminent danger to the public health, there is no basis for depriving Morris & Dickson of the procedural safeguards necessary to ensure that it is not erroneously deprived of its registration. *See Mathews v. Eldridge*, 424 U.S. 319, 335 (1976); *United States v. James Daniel Good Real Property*, 510 U.S. 43, 62 (1993) ("To establish exigent circumstances, the Government must show that less restrictive measures . . . would not suffice to protect the Government's interests"). The License Suspension Order thus constitutes a deprivation of Morris & Dickson's property and liberty interests without due process of law.

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For all of these reasons, Morris & Dickson is likely to succeed on the merits of its challenges. DEA's License Suspension Order is unnecessary to prevent harm to the public, is arbitrary and capricious, and violates due process.

II. Morris & Dickson And Its Customers Will Suffer Irreparable Harm Absent A TRO

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A TRO is necessary to prevent irreparable harm to Morris & Dickson and its customers. A showing of significant loss of customers and goodwill qualifies as an irreparable injury. *BellSouth Telecomms. v. MCIMetro Access Trans. Servs.*, 425 F.3d

964, 970 (11th Cir. 2005); *Armour & Co. v. Freeman*, 304 F.2d 404, 406 (D.C. Cir. 1962)

(loss of goodwill and "loss of profits which could never be recaptured" constituted irreparable harm); *Alfv. Donley*, 666 F. Supp. 2d 60, 70 (D.D.C. 2009) ("[i]njury to reputation or goodwill is not easily measurable in monetary terms, and so often is viewed as irreparable" (quoting *Wright & Miller*, 11A Fed. Prac. & Proc. § 2948.1)). *Patriot, Inc. v. US. Dep't of Housing & Urban Dev.*, 963 F. Supp. 1, 5 (D.D.C. 1997) ("[P]laintiffs have demonstrated irreparable harm in damage to their business reputation."). Costs incurred, and "time and person power spent," because of unlawful agency action also constitute irreparable losses. *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997).

Here, the harm suffered by Morris & Dickson at the hands of DEA is certain, immediate, and irreparable. Morris & Dickson will lose some customers, likely permanently, in the absence of a TRO. *Giacomin Decl.*, ¶¶ 20-22. The Lakeland facility's inability to distribute controlled substances will cause considerable damage to Morris & Dickson's reputation and ability to maintain and attract customers. *Id.*, ¶ 20. Shipments of vitally important controlled substances, desperately needed by seriously ill or terminal patients, will-at a minimum-need to be rerouted from other Morris &

Dickson distribution

facilities, resulting in pointless and, in some instances, serious delays. *Id.*, ¶¶ 7-9.

Moreover, Morris & Dickson's customers would not want to order controlled

substances from one facility and non-controlled substances from another facility. *Id.*, ¶

20. To avoid

inconvenience and splitting volume between different distributors, many of these customers will likely redirect orders to other wholesale distributors, resulting in serious and permanent loss of revenue and customers for the Morris & Dickson.

Id., ¶ 20-22.

The License Suspension Order would also impose significant unrecoverable costs on Morris & Dickson. The

effort required to reroute controlled substances from other distribution centers is massive.

Id., ¶ 7. Just as the rerouting of trains carrying hazardous waste around the District of Columbia constituted irreparable harm in *CSX Transp., Inc. v. Williams*, 406 F.3d 667, 673 (D.C. Cir. 2005), the rerouting of distribution of controlled substances required by the License Suspension Order would "significantly decrease the capacity and flexibility" of the Morris & Dickson drug distribution system, and would cause troubling delays.

The harm to Morris & Dickson and its customers cannot be repaired if Morris & Dickson must wait for a decision on a motion for a preliminary injunction or must wait to seek restoration of its registration through DEA's administrative process. When DEA serves an License Suspension Order, there is no statutory deadline for scheduling a hearing or determining when DEA will issue a final determination. *See* 21 U.S.C. § 824(d). Even with an License Suspension Order in effect, proceedings before DEA can take up to a year or more to be resolved. *Cf. e.g.*, Nicholas A. Sychak, d/b/a Medicap Pharmacy, DEA Docket No. 99-10, 65 Fed. Reg. 75,959 (Dec. 5, 2000) (registration was suspended on December 14, 1998,

administrative hearing held on July 12 and 13, 1999, and final order issued on December 5, 2000). Morris & Dickson will be irreparably harmed if the company must wait for two days, let alone two years, to resolve this matter.

III. The Balance Of Hardships Also Favors Issuance Of A TRO

The balance of hardships also supports entry of a TRO. Granting a TRO will harm

no one, including DEA. As explained above, *see supra* at 15-24, Morris & Dickson's continued registration poses no imminent threat to public health. Morris & Dickson no longer even distributes controlled substances to the pharmacies identified in the License Suspension Order, it has suspended controlled-substance shipments to other pharmacies it believes pose a risk of diversion, and it stands ready and willing to suspend shipments to any pharmacy DEA identifies as likely to be engaged in diversion. *See supra* at 2. In these circumstances, no harm will result from requiring DEA to follow its normal administrative procedures for revoking a distributor's registration-procedures that can be expedited (as long as DEA does not deprive Morris & Dickson of its constitutional right to due process).

DEA's own conduct makes clear that the agency recognizes that a modest further delay will cause it no harm. DEA served an administrative inspection warrant against Morris & Dickson on October 25, 2011. Ex. J. It then waited over three months to issue the License Suspension Order. Additionally, DEA has known how Morris & Dickson's SOM Program operates since

2009, when it inspected Morris & Dickson facilities pursuant to the 2008 MOA. *See* Mone

Decl. ¶¶ 28-29.

On the other hand, for all of the reasons discussed above, Morris & Dickson will suffer severe and irreparable harm to its business and its reputation if the License Suspension Order is left in place. The balance of hardships thus tips decidedly in favor of Morris & Dickson.

IV. The Public Interest Will Be Served By Issuance Of A TRO

The public interest weighs heavily in favor of granting injunctive relief to Morris & Dickson. As explained above, *see supra* at 15-24, Morris & Dickson's continued registration poses no imminent threat to public health. The License Suspension Order would not stem the diversion of controlled substances in Florida. Just as if the state police tried to halt illegal drag racing

by shutting down a single gas station, the License Suspension Order would not achieve its claimed objective- any Lakeland facility customers who might in the future pose a risk of diversion would simply purchase their supplies from other providers. Indeed, because Morris & Dickson's anti-diversion program is one of the best among wholesale drug distributors nationwide (*see* Mone Decl. 29), the shift to other distributors could actually harm the public. The delays caused by the restrictions on the Lakeland facility would also harm the public. *See supra* at 25-27. Finally, "there is an overriding public interest ... in the general importance of an agency's faithful[ly] adher[ing] to its statutory mandate," *Jacksonville*

Port Auth. v. Adams, 556 F.2d 52, 59 (D.C. Cir. 1977), as DEA has failed to do. For all of

these reasons, the public interest weighs heavily in favor of granting a TRO.

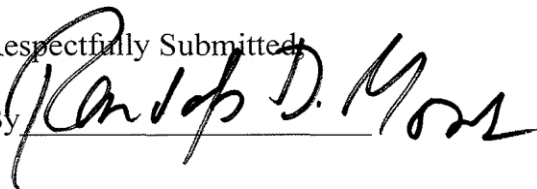
CONCLUSION

For the reasons set forth above, Morris & Dickson requests that this Court issue a TRO

that prevents DEA from enforcing the License Suspension Order pending the resolution of a motion for a preliminary injunction (or other judicial proceedings).

Respectfully Submitted,

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